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09/375,514 08/17/99 REED

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EXAMINER

SCHMIDT, M

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

06/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/375,514

Applicant(s)

REED, JOHN C.

Examiner

Mary Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-63 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 53-63 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER
PATENT ANALYST

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 7.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: ____

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DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: (1) Lines 10-14 of the first page of the specification as filed need to be canceled since the Amendment to the first line of the specification (Amendment A1) provides duplicate information. (2) Also, the status of allowed Applications 08/080,285 and 08/465,485 in the first line of the specification needs to include the issued patent numbers. (3) Further, the brief description of the drawings needs to reference the sequences in the figures by sequence identifiers.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 53 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 53 is indefinite for the language "consisting of from 10-35 bases and comprising" SEQ ID NO:17 since SEQ ID NO:17 is 18 bases long and thus the 10-17 base long anticodes as claimed could not comprise SEQ ID NO:17.

Claim 55 is indefinite for the language "wherein said anticodon oligomer is ... complementary to a portion of the region of the splice acceptor site or splice donor site of the pre-mRNA encoding the bcl-2 gene" since it is not clear how many splice acceptor or donor sites there are in the disclosed bcl-2 gene sequence. If there is more than one such site, the claim as written is indefinite.

4. Claims 54-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 54-63 are drawn to anticodon oligomers to the pre-mRNA, splice donor or splice acceptor sites, 5' UTR of the mRNA or any portion of the mRNA of bcl-2. The specification as filed teaches antisense to the human bcl-2 gene but does not disclose the gene sequence from other species of bcl-2 nor antisense to said sequences.

One skilled in the art would not have been in possession of the scope of antisense anticodes claimed to any bcl-2 gene in the art at the time the invention was made. Design of an

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antisense oligonucleotide to a target gene sequence is dependent on knowing the target gene sequence. The scope of possible bcl-2 genes was not disclosed at the time the invention was made such that one skilled in the art would have a representative number of species in which to design antisense to from the genus of all possible bcl-2 gene sequences.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

6. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.7

Claims 53-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 5,831,066. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims drawn to anticodon oligonucleotides directed to bcl-2 mRNA, and specifically the composition of SEQ ID NO:17, are encompassed by the methods and kits of '066 which include anticodon oligonucleotides to bcl-2mRNA and the sequence of SEQ ID NO:17.

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7. Claims 53-63 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,040,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims drawn to anticodon oligonucleotides directed to bcl-2 mRNA, and specifically the composition of SEQ ID NO:17, are encompassed by the methods of '181 which include anticodon oligonucleotides to bcl-2 mRNA and the sequence of SEQ ID NO:17.
8. The claims are free of the prior art, antisense to bcl-2, prior to December 22, 1988, the filing date of U.S. Application No. 07/288,692.
9. Should all claims be found allowable, the prevalence of antisense to bcl-2 in the post art would suggest that there will be a high potential for interference of any broad claims to human bcl-2.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

M. M. Schmidt
June 18, 2001


ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER